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November 22, 2024

Honorable Michael E. Farbiarz, U.S.D.J.
Frank R. Lautenberg U.S. Post Office & Courthouse
2 Federal Square
Newark, New Jersey 07102

Re: *In re Celgene Corp. Securities Litigation*, Case No. 2:18-cv-04772-MEF-JBC

Dear Judge Farbiarz:

We, along with Lead Counsel, represent Lead Plaintiff AMF Tjänstepension AB (“Plaintiff” or “AMF”) and the Class in this matter. We write in response to Defendants’ letters dated November 15, 2024 (D.E. 348) and November 19, 2024 (D.E. 351) seeking leave to belatedly file a motion under Federal Rule of Civil Procedure 12(c).

Defendants’ Post-Summary Judgment Request for Leave to File a Rule 12(c) Motion Is Untimely and Prejudicial and Should Be Denied

Defendants’ eleventh-hour request for leave to file a Rule 12(c) motion—brought more than *three years* after the close of fact discovery and following protracted summary judgment briefing—should be denied. As Defendants acknowledge, “the deadline for dispositive motions passed under the case management schedule.” D.E. 348 at 1 n.1. Indeed, that deadline lapsed nearly *two years* ago. *See* D.E. 225 (ordering the parties to seek leave to file summary judgment or “any others dispositive motions” by January 27, 2023). Defendants offer no explanation whatsoever for their delay, nor could they.

Defendants have clearly been aware of these arguments since the outset of this case. In their February 2019 motion to dismiss, Defendants specifically argued that the October 2017 Statements were protected by the PSLRA safe harbor. *See* D.E. 52-1 at 58-61; D.E. 71 at 28-32. Judge Vazquez correctly rejected this argument the first time it was made, which is law of the case. D.E. 75 at 37-39. Defendants fail to demonstrate that this ruling was “clearly erroneous” or “would work a manifest injustice” such that the Court should “revisit” this decision. *Hertz Corp. v.*

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Frissora, 2023 WL 4173031, at *5-6 (D.N.J. June 26, 2023) (citing *Pub. Interest Research Grp. of N.J., Inc. v. Magnesium Elektron, Inc.*, 123 F.3d 111, 116 (3d Cir. 1997)).¹

Since that time, Defendants have had no fewer than **8 opportunities** to raise this safe harbor argument again, or at least preview that they intended to file a Rule 12(c) motion on this issue. *See* D.E. 231 (pre-summary judgment motion letter challenging October 2017 Statements); D.E. 245 (first summary judgment motion challenging October 2017 Statements); D.E. 272 (first summary judgment oral argument); D.E. 278 (second summary judgment motion challenging October 2017 Statements); D.E. 294 (second summary judgment oral argument); D.E. 295 (letter brief regarding Curran’s scienter for the October 2017 Statements); D.E. 315 (second letter brief regarding October 2017 Statements); D.E. 335 (oral argument regarding October 2017 Statements). In fact, at the October 10, 2024 hearing, Your Honor specifically asked Defendants’ counsel whether there were “any big issues that . . . you can see now that are the kind of issues that will take my attention up?” D.E. 335 at 47. In response, counsel cited only their bifurcation motion and potential *Daubert* motions, stating that they were “[t]he only thing that comes to mind.” *Id.* at 48-49. Defendants also chose not to raise their contemplated motion during the October 15, 2024 case management conference with Judge Clark, when the parties discussed the timing of the Joint Pretrial Order. *See* D.E. 334.²

Given Defendants’ inexplicable delay, Defendants cannot establish good cause for modifying the Court’s scheduling order regarding the timing for dispositive motions. Fed. R. Civ. P. 16(b)(4); *Sabatino v. Union Twp.*, 2013 WL 1622306, at *4 (D.N.J. Apr. 15, 2013) (“Whether ‘good cause’ exists under Rule 16 hinges to a large extent on the diligence, or lack thereof, of the moving party [a]bsent diligence, there is no ‘good cause.’”); *Brown v. Wilson*, 2024 WL 4458525, at *3 (W.D. Pa. Oct. 10, 2024) (“carelessness, or attorney error, which might constitute ‘excusable neglect’ under Rule 6(b), is insufficient to constitute ‘good cause’ under Rule 16(b)”);

¹ Defendants’ only basis for revisiting Judge Vazquez’s safe harbor analysis is that “[t]he record now includes all of the cautionary language,” D.E. 351 at 1 n.1, but Defendants previously argued that Celgene’s purported cautionary language was judicially noticeable, D.E. 52-1 at 1 n.1, and they attached Celgene’s February 10, 2017 Form 10-K containing the relevant risk disclosures to their motion to dismiss. *See* D.E. 52-16; D.E. 52-1 at 14, 55, 59 (citing cautionary language). Therefore, the issue of whether the October 2017 Statements are protected by the safe harbor was “actually decided, either expressly or by implication” by Judge Vazquez, justifying application of the law of the case doctrine. *In re City of Philadelphia Litig.*, 158 F.3d 711, 718 (3d Cir. 1998); *see also MTR Gaming Grp., Inc. v. Arneault*, 2015 WL 136563, at *9 (W.D. Pa. Jan. 9, 2015) (denying Rule 12(c) motion that “incorporates virtually all of the same arguments as were raised in the Rule 12(b)(6) motion and . . . is based on essentially the same record”).

² Defendants had yet another opportunity to raise this argument when Plaintiff filed the Third Amended Complaint (D.E. 175, “TAC”). *See* D.E. 145 at 5 n.3 (stating that “Defendants will [file] a motion to dismiss if leave to amend is granted”). They declined to do so.

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Riggins v. Walter, 279 F.3d 422, 427-28 (7th Cir. 1995) (affirming denial of leave to file Rule 12(c) motion because “Rule 12(c) does not restrict the court’s discretion under Rule 16(b)” and party “failed to offer any reason why he could not have filed his motion before the deadline”).

Even if the Court were to overlook Defendants’ egregious lack of diligence, Rule 12(c) only permits a party to file a motion “[a]fter the pleadings are closed—but early enough not to delay trial” Fed. R. Civ. P. 12(c); *see* 5C Charles Alan Wright & Arthur Miller, *Federal Practice and Procedure* § 1367 (3d ed. 2024) (“If a party engages in **excessive delay** before moving under Rule 12(c), the district court may refuse to hear the motion on the ground that its consideration will delay or interfere with the commencement of the trial.”).

Courts regularly deny leave to file Rule 12(c) motions that will delay trial or prejudice the non-moving party, particularly where the moving party inexcusably delays seeking leave to file the motion. *See, e.g., Brown*, 2024 WL 4458525, at *3 (denying leave to file Rule 12(c) motion where “Defendants—without explanation—waited until less than three months before the [] trial” to seek leave, “**despite the various conferences with the Court, opportunities for legal argument, and motions and briefs filed in this case**”); *Transource Pa., LLC v. DeFrank*, 2023 WL 8456121, at *3 (M.D. Pa. Dec. 6, 2023) (denying leave where “Defendants were aware of the facts of these pleadings for over a year before they filed the instant [Rule 12(c)] motion”); *Badillo-Rubio v. RF Construction, LLC*, 2021 WL 461590, at *2 (M.D. La. Feb. 9, 2021) (“The Court finds that the instant motion is a blatant attempt to delay the trial” and there is “**no reason why th[e] motion could not have been filed sooner**.”); *Jones v. Town of Quartzsite*, 2014 WL 12617038, at *2 (D. Ariz. Feb. 24, 2014) (denying leave where “[t]he excessive delay and timing of the motion suggests Defendants strategically waited to file the motion”); *In re CCT Comms., Inc.*, 2011 WL 5509197, at *2-3 (Bankr. S.D.N.Y. Nov. 10, 2011) (denying leave where moving party “**has not offered an acceptable reason for waiting until now** to make a motion that might have curtailed discovery and prior motion practice”); *see also Siemens Westinghouse Power Corp. v. Dick Corp.*, 219 F.R.D. 552, 554 (S.D.N.Y. 2004) (rejecting “piecemeal consideration of successive motions for summary judgment” where party “has not raised any new facts or arguments which it could not have raised in the first round of briefing”).

There can be no doubt that Plaintiff will be prejudiced if Defendants are granted leave to file their untimely Rule 12(c) motion at this late stage of the case, as it will delay the trial in this six-year old case and divert important resources away from ongoing trial preparations. This has already occurred, as Defendants strategically filed their November 15, 2024 letter one day after serving their portions of the Joint Pretrial Order, necessitating this response while Plaintiff simultaneously responds to Defendants’ contentions of fact, deposition designations, and trial exhibits. *See Brown*, 2024 WL 4458525, at *2 (“[O]rdering Plaintiff to respond to Defendants’ proposed Rule 12(c) motion at this juncture, and thus requiring the re-litigation of portions of this case so close to trial, in the midst of meeting the other deadlines imposed on the parties by the Court’s [] Pretrial Order, would also be prejudicial to the Plaintiff, as it would undoubtedly hamper his ability prepare for trial.”). Allowing a defendant to file seriatim summary judgment and Rule 12(c) motions would delay trial indefinitely. Enough is enough.

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None of Defendants' cited cases supports granting leave under these circumstances. For example, in *American Trucking*, the defendants' multi-year delay in bringing a dispositive motion based on a statutory exemption was excused by the fact that "neither the [defendants] nor anyone familiar with this lawsuit actually knew about the [exemption]," "[c]ounsel for Defendants have fallen on their swords; they admit that they were unaware of the [exemption]" and "two decades had passed [since the statute was enacted], and institutional memories had obviously faded." *Am. Trucking Assocs., Inc. v. N.Y. State Thruway Auth.*, 238 F. Supp. 3d 527, 540-41 (S.D.N.Y. 2017). Here, Defendants previously asserted the very arguments they seek to renew, had numerous opportunities to raise these arguments at summary judgment, and offer no explanation whatsoever for their delay. In *Bey*, the parties had not "been able to agree on a proposed joint pre-trial order," and so the court found that the Rule 12(c) motion was timely. *Bey v. City of New York*, 2010 WL 3910231, at *3 (S.D.N.Y. Sept. 21, 2010). Here, the Joint Pretrial Order will be filed on December 9, 2024 and a final pretrial conference is scheduled for December 20, 2024. D.E. 334. Additionally, the Rule 12(c) motion in *Bey* was premised on *res judicata* arguments, and the court found that consideration of the motion was supported by "the strong public policy in economizing the use of judicial resources by avoiding relitigation [of previously decided issues] . . . regardless of any alleged waiver or forfeiture of the defense." *Bey*, 2010 WL 3910231, at *6. No such policy considerations apply here. Rather, countervailing considerations of "promot[ing] finality and judicial economy" support **avoiding** the relitigation of an issue already decided by Judge Vazquez. *Pub. Int. Rsch. Grp.*, 123 F.3d at 116. Defendants' other cases are similarly inapposite. See *PDX N., Inc. v. Comm'r N.J. Dep't of Lab. & Workforce Dev.*, 978 F.3d 871, 880 (3d Cir. 2020) (allowing Rule 12(c) motion filed just two days after pleadings closed); *Ferrari Club of Am., Inc. v. Bourdage*, 2017 WL 6419061, at *1 (W.D.N.Y. Apr. 25, 2017) (allowing 12(c) motion to address issues raised, for the first time, in plaintiff's pretrial statement).

Given the numerous opportunities for Defendants to reassert their safe harbor arguments—which were already considered and rejected by Judge Vazquez—including in multiple rounds of summary judgment briefing, the Court should deny their untimely request to derail this litigation.

The October 2017 Statements Are Not Protected by the Safe Harbor

Even if the Court were to entertain Defendants' untimely request, their Rule 12(c) motion fails on the merits. The PSLRA safe harbor protects only those statements that are forward-looking and accompanied by meaningful cautionary language, or for which Plaintiff fails to establish that the defendants had actual knowledge that the statement was false.³ 15 U.S.C. § 78u-5(c). None of the challenged statements satisfy these requirements.

The October 2017 Statements Were Not Forward-Looking

The October 2017 Statements touting the timeline for the NDA submission include representations of current fact that are not entitled to safe harbor protection. These statements

³ Defendants do not dispute that they had actual knowledge of the risks regarding the New Drug Application ("NDA") at the time of the October Statements. See D.E. 348.

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communicated to the market the **current** state of the Ozanimod data and Celgene's **present** ability to file a complete NDA by December 2017. As such, they "were based on misrepresented present facts," *In re Novo Nordisk Sec. Litig.*, 2018 WL 3913912, at *9 (D.N.J. Aug. 16, 2018)—i.e., the NDA was not going to be ready for submission by year-end 2017 without additional testing or the FDA-granted exception. *See id.* at *3, 9 (statement that "it's our anticipation that if and when we get approval for Tresiba in the US . . . that will allow us to achieve 100% or more top-line growth in the diabetes market" not protected by safe harbor because "[d]efendants were [allegedly] aware of negative issues related to Tresiba," including that it "showed 'no added benefit' over existing insulin drugs"); *see also Rihn v. Acadia Pharm. Inc.*, 2016 WL 5076147, at *7 (S.D. Cal. Sept. 19, 2016) (holding that defendants' "representation[s] of present conditions pertaining to the NDA process" were not protected by safe harbor).

In making Statement 3 on October 28, 2017 (i.e., just two days after Celgene lowered its Otezla guidance and its stock price sank by 16%, TAC ¶¶ 427-38), Defendant Martin stated that Celgene is "**working hard as we speak**" to file the NDA by year-end (TAC ¶ 414)—a present-tense declaration that misleadingly indicated that Celgene's preparations for the NDA were running smoothly, with no substantial challenges standing in the way of a December 2017 submission. This was a misrepresentation of the current state of affairs and is not protected by the safe harbor. *See In re Viropharma, Inc. Sec. Litig.*, 2003 WL 1824914, at *7 (E.D. Pa. Apr. 7, 2003) (statements not forward-looking because "these statements when read in context are statements conveying to the market **the current status of clinical trials and the NDA** . . . [t]he truth or falsity of . . . these statements was determinable at the time they were made"). Martin's statement also hyped the fact that "the RADIANCE and SUNBEAM study will form the basis of our submission to the FDA." *Id.* ¶ 414. In rejecting Defendants' safe harbor argument at the motion to dismiss stage, Judge Vazquez found that "the fact that Defendants told investors about the positive clinical study results but failed to disclose the Metabolite discovery was misleading." D.E. 75 at 38-39. Therefore, Martin's statement is actionable independent of the fact that it referenced the forthcoming NDA. *See Curran v. Freshpet, Inc.*, 2018 WL 394878, at *4 (D.N.J. Jan. 12, 2018) (safe harbor "does not apply to a mixed present/future statement . . . with respect to the part of the statement that refers to the present").

Statement 2 also makes reference to the current state of affairs. The first slide in the investor presentation, entitled "Q3 2017 I&I Franchise **Results**," boasts the fact that Celgene is "**Preparing** for regulatory submission to the FDA by year-end" and that "[g]lobal launch readiness activities [were] underway." TAC ¶ 407. Again, these statements were rooted in the present and falsely suggested to investors that all was well with the NDA's current progress (when, of course, it was far from it). *See* D.E. 75 at 38 (at the time of the October 2017 Statements, "Celgene had discovered the Metabolite, knew that additional testing was required, and that . . . without the necessary Metabolite testing, the contemplated NDA was dead on arrival").

Even when viewed as "mixed present/future statement[s]," *Freshpet*, 2018 WL 394878 at *4, because the October 2017 statements "advert to a particular current fact," they are not protected by the safe harbor. *Inst. Inv. Grp. v. Avaya, Inc.*, 564 F.3d 242, 256 (3d Cir. 2009); *see In re Cigna Corp. Sec. Litig.*, 2005 WL 3536212, at *11 (E.D. Pa. Dec. 23, 2005) ("on track" statements held "false because CIGNA knew there were serious technological flaws and significant delays"); *Rihn*,

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2016 WL 5076147, at *6-7 (“statements that Acadia remained ‘on track’ to submit the NDA by the deadline” were not forward-looking because such “assurances were representations about the **current** state of affairs with respect to the NDA process, which were within Defendants’ knowledge and control”) (emphasis in original).

The Safe Harbor Does Not Protect Omissions

Even if portions of the October 2017 Statements are deemed forward-looking, because “plaintiffs [] challenge defendants’ alleged **omission** of present facts with respect to the challenged statements, [the] PSLRA’s safe harbor does not apply.” *Roofers’ Pension Fund v. Papa*, 2018 WL 3601229, at *7 (D.N.J. July 27, 2018). Courts in this Circuit have consistently held that “omissions of existing facts or circumstances are not forward-looking, and thus do not qualify for the safe harbor protection.” *In re Viropharma Inc. Sec. Litig.*, 21 F. Supp. 3d 458, 471 (E.D. Pa. 2014); *see, e.g., Freshpet*, 2018 WL 394878, at *5 (“Defendants’ statements . . . are not subject to the PSLRA safe harbor . . . because they . . . were made misleading by material omissions”); *In re AT&T Corp. Sec. Litig.*, 2002 WL 31190863, at *14 (D.N.J. Jan. 30, 2002) (“**[T]he safe harbor provision does not afford corporations a free pass to lie to investors . . . purposeful omission[s] . . . do not qualify as forward-looking statements**”); *SEB Inv. Mgmt. AB v. Endo Int’l, PLC*, 351 F. Supp. 3d 874, 901 (E.D. Pa. 2018) (“[Defendant]’s statements appear to be forward-looking **But, the statements are incomplete** [B]ecause they did not disclose facts that contradicted them, the statements do not qualify for protection under the safe harbor provision.”).

Each of the October 2017 Statements omitted the then-existing material facts that: (1) Celgene belatedly discovered a highly active Metabolite; (2) this discovery and the required follow-on testing threatened the NDA submission timeline; and (3) there was a substantial risk that the FDA would refuse to file the NDA without the test results. D.E. 290-1; D.E. 290-2; D.E. 310 at 35-41. Because Plaintiff “challenge[s] [D]efendants’ alleged omission of present facts . . . , the PSLRA’s safe harbor does not apply.” *Freshpet*, 2018 WL 394878, at *4.

There Is No Meaningful Cautionary Language

Defendants’ safe harbor argument also fails because none of the October 2017 Statements were accompanied by adequate cautionary language. “To suffice, the cautionary statements must be substantive and **tailored to the specific** future projections, estimates or opinions . . . which the plaintiffs challenge”; it cannot be mere boilerplate. *Semerenko v. Cendant Corp.*, 223 F.3d 165, 182 (3d Cir. 2000); *see In re Enzymotec Sec. Litig.*, 2015 WL 8784065, at *7, 11 (D.N.J. Dec. 15, 2015) (“cautionary language must be” “**specific** and touch upon the subject matter of the alleged misrepresentation in order for the safe harbor to apply”); *see also Kline v. First W. Gov’t Sec., Inc.*, 24 F.3d 480, 489 (3d Cir. 1994) (“Not just any cautionary language will trigger application of the [bespeaks caution] doctrine. Instead, **disclaimers must relate directly to that on which investors claim to have relied.**”)

The cautionary language that Defendants claim excuses the October 2017 Statements does not address the specific risks that Defendants concealed at the time of their statements. It merely

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stated, in boilerplate fashion—and without reference to Ozanimod or any other specific drug—that “***In general***, delays or rejections may be encountered during any stage of the regulatory process if the clinical or other data fails to demonstrate compliance with a regulatory agency’s requirements for safety, efficacy and quality.” D.E. 52-16 (10-K filed Feb. 10, 2017) at 17; D.E. 278-8 (10-Q filed Oct. 26, 2017) at 407. This self-designated “general[ized]” statement (*id.*) is as unmeaningful as a corporate risk warning can get. As Plaintiff argued at the motion to dismiss stage, this boilerplate warning regarding the “regulatory process” makes ***no mention of the Metabolite***, the required additional testing that endangered the NDA, or the fact that Celgene had sought an exception from the FDA to supplement the NDA with additional data after December 2017. *See, e.g., In re PDI Sec. Litig.*, 2005 WL 2009892, at *13 (D.N.J. Aug. 17, 2005) (“While the cautionary statements seemingly have a connection to the issue of Ceftin inventory, it is not so clear to this Court that the accompanying warnings negate any potentially misleading effect that omissions concerning [illegal] marketing . . . would have . . .”).

Indeed, “the fact that [Celgene’s] vague cautionary language ***never changed*** [during the Class Period] strongly suggests that it was not ‘tailored to the specific future projection.’” *In re Hertz Global Holdings, Inc. Sec. Litig.*, 2017 WL 1536223, at *15 (D.N.J. Apr. 27, 2017) (quoting *Slayton v. Am. Exp. Co.*, 604 F.3d 758, 773 (2d Cir. 2010) (“The consistency of the defendants’ language over time despite the new information they received . . . belies any contention that the cautionary language was tailored to the specific future projection.”)). In *Hertz*, Judge Arleo held that the safe harbor did not apply because “the cautionary language remained the same” even after defendants knew of the company’s accounting errors. 2017 WL 1536223, at *15 (“The same sentence that appeared in the February 25, 2013 Form 8–K continued to appear after Hertz announced that it had to . . . adjust its previously issued financial statements in the 2014 Form NT–10Q on May 13, 2014”); *accord Sgalambo v. McKenzie*, 739 F. Supp. 2d 453, 478 (S.D.N.Y. 2010) (no safe harbor where disclaimer of general factors that might cause actual results to differ “remained constant throughout the Class Period”).

Here, the vague cautionary language that Defendants claim immunized their misrepresentations remained static for years—it was repeated ***verbatim*** in each of Celgene’s Forms 10-K between 2014 and 2018.⁴ This language was never updated to reflect the discovery of the Metabolite, the consequent need for additional testing that would not be completed by December 2017, and the uncertainty surrounding Celgene’s request to the FDA that it be permitted to supplement the NDA with additional data after December 2017. In fact, Celgene’s purported cautionary language remained the same even ***after*** Defendants filed a knowingly deficient NDA that lacked the required Metabolite data, confirming that it was not tailored to the specific misrepresentations at issue. *See* D.E. 52-20 (Feb. 7, 2018 10-K) at 19. Unlike in Defendants’ cited cases, this cautionary language is not “meaningful” as required to invoke the safe harbor. *Cf.*

⁴ Compare D.E. 52-24 (Feb. 13, 2014 10-K) at 17 (“Delays or rejections may be encountered during any stage of the regulatory process if the clinical or other data fails to demonstrate compliance with a regulatory agency’s requirements for safety, efficacy and quality.”), with D.E. 52-25 (Feb. 20, 2015 10-K) at 18 (same), and D.E. 52-19 (Feb. 11, 2016 10-K) at 18 (same), and D.E. 52-16 (Feb. 10, 2017 10-K) at 17 (same), and D.E. 52-20 (Feb. 7, 2018 10-K) at 19 (same).

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In re Discovery Labs. Sec. Litig., 2006 WL 3227767, at *16 (E.D. Pa. Nov. 1, 2006) (safe harbor applied where “the list of likely risks [in the cautionary statements] changed over time and from one press release to another, undoubtedly in an attempt to make the cautionary language ‘substantive and tailored.’”).

Finally, the safe harbor does not immunize the October 2017 Statements because the purported cautionary language failed to disclose that the risk of “delays or rejections” in “the regulatory process” (D.E. 52-16 at 17; D.E. 278-8 at 407) had “already materialized” due to Celgene’s discovery of the Metabolite in the midst of Phase III trials and consequent need to conduct additional testing that endangered the December 2017 NDA filing. *Williams v. Global Med., Inc.*, 869 F.3d 235, 241 (3d Cir. 2017). As the Third Circuit has explained, “a company may be liable under Section 10(b) for misleading investors when it describes as hypothetical a risk that has already come to fruition.” *Id.* at 242; *see, e.g., Enzymotec*, 2015 WL 8784065, at *7, 11 (no meaningful cautionary language because “even though Defendants warned generally of significant and increasing government regulations . . . these risks had already come to pass and [] it was therefore unreasonable to make generalized warnings when Defendants knew, or should have known, of the specific regulations and their likely effect”).

Thus, Defendants’ generalized cautionary language, which could apply to any drug and made no mention of these known risks, cannot shield them from liability.

* * *

For all the above reasons, the Court should deny Defendants’ attempt to bring a pleadings motion at this late stage of this litigation, particularly since the very arguments Defendants seek to make have already been rejected, and because the Court allowed extensive additional summary judgment briefing on the October 2017 Statements, yet Defendants chose not to make these arguments. The Court should deny their request for leave to file a belated Rule 12(c) motion.

We thank Your Honor for the Court’s attention to this matter.

Respectfully submitted,

CARELLA, BYRNE, CECCHI,
BRODY & AGNELLO

/s/ *James E. Cecchi*

James E. Cecchi